

Environmental Protection Agency

§ 155.53

videographic record. Written material may be submitted in paper or electronic form.

(3) Submitters must clearly identify the source of any submitted data or information.

(4) Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

(d) For the purposes of this subpart, the provisions of subpart B do not apply.

§ 155.52 Stakeholder engagement.

In addition to the public participation opportunities described in §155.50 and §155.53(c), the Agency may meet with stakeholders regarding a forthcoming or ongoing registration review. For example, before conducting a pesticide's registration review, the Agency may consult with registrants or pesticide users regarding the use and usage of the pesticide. The Agency may consult with registrants, pesticide users, or other persons during a pesticide's registration review with regard to developing risk management options for a pesticide. The Agency may informally consult with officials of Federal, State or Tribal agencies regarding a forthcoming or ongoing registration review.

(a) *Minutes of meetings with persons outside of government.* Subject to paragraph (c) of this section, if the Agency meets with one or more individuals that are not government employees to discuss matters relating to a registration review, the Agency will place in the docket a list of meeting attendees, minutes of the meeting, and any documents exchanged at the meeting, not later than the earlier of:

(1) 45 days after the meeting; or

(2) The date of issuance of the registration review decision.

(b) *Exchange of documents or other written material.* In the course of a meeting with a person outside of government, the Agency or that person may provide the other with a copy of a document or other written material that has not yet been released to the

public. The Agency will place a copy of any such document or other written material in the docket along with the minutes of the meeting where the materials were exchanged.

(c) *Confidential business information.* The Agency will identify, but not include in the docket, any confidential business information whose disclosure is prohibited by FIFRA section 10.

[71 FR 45732, Aug. 9, 2006, as amended at 73 FR 75596, Dec. 12, 2008]

§ 155.53 Conduct of a pesticide's registration review.

The Agency will review data and information described in §155.50(a), (b), and (c) or submitted in response to a Data Call-In notice that it believes should be considered in the pesticide's registration review.

(a) *Assess changes since a pesticide's last review.* The Agency will assess any changes that may have occurred since the Agency's last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration. The Agency will consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements. The Agency will consider whether any new data or information on the pesticide, including any data or information submitted under §155.50 or in response to a Data Call-In notice, warrant conducting a new risk assessment or a new risk/benefit assessment. The Agency will also consider whether any new data or information regarding an individual pesticide product, including any data or information submitted under §155.50 or in response to a Data Call-In notice, such as data or information about an inert ingredient in the pesticide product or other information or data relating to the composition, labeling or use of the pesticide product, warrant additional review of a pesticide product's registration.

(b) *Conduct new assessments as needed.*

(1) Active ingredient(s) in the registration review case. If the Agency finds that a new assessment of the pesticide is needed, it will determine whether it

can base the new assessment on available data or information, including data or information submitted under § 155.50 or in response to a Data Call-In notice. If sufficient data or information are available, the Agency will conduct the new risk assessment or risk/benefit assessment. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(2) Individual product registrations. If the Agency finds that additional review of an individual product's registration is needed, it will review the pesticide product label, confidential statement of formula, product-specific data, or other pertinent data or information, as appropriate, to determine whether the registration of the individual product meets the FIFRA standard for registration. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(c) *Public participation during a pesticide's registration review.* The Agency will generally make available for public review and comment a draft risk assessment for a pesticide if a new risk assessment has been conducted. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of the draft risk assessment and provide a comment period of at least 30 calendar days. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a revised risk assessment, an explanation of any changes to the proposed document, and its response to comments. If the revised risk assessment indicates risks of concern, the Agency may, in the notice announcing the availability of the revised risk assessment, provide a comment period of at least 30 calendar days for the public to submit suggestions for mitigating the risk identified in the revised risk assessment.

(1) The Agency might not request comments on a draft risk assessment in cases where the Agency's initial screening of a pesticide indicates that it has low use/usage, affects few if any

stakeholders or members of the public, poses low risk, and/or requires little or no risk mitigation. In such cases, the Agency will make a draft risk assessment available for public review and comment when it issues a proposed decision on the registration review case.

(2) If the Agency finds that it is not necessary to conduct a new risk assessment, it will issue a proposed decision on the registration review case as described in § 155.58.

§ 155.56 Interim registration review decision.

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in § 155.58 when issuing an interim registration review decision.

§ 155.57 Registration review decision.

A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA.

§ 155.58 Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide's registration review docket the Agency's proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things: